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REPORT
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IMMUNOSUPPRESSIVE DRUG THERAPY ACT OF 1986

AUGUST 11, 1986.—Ordered to be printed

Mr. HATCH, from the Committee on Labor and Human Resources, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 2536]

The Committee on Labor and Human Resources, to which was referred the bill (S. 2536) to provide for block grants to States to pay the costs of immunosuppressive drugs for organ transplant patients, having considered the same, reports favorably thereon with amendments and recommends that the bill as amended do pass.

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I. SUMMARY OF THE BILL

As reported by the Committee, S. 2536 would amend the Public Health Service Act to add a new part C to title XIX (Block Grants). The new part C would establish an Immunosuppressive Drug Ther-

apy Block Grant. The bill authorizes appropriations of $15 million a year for FY 1987 through FY 1989. For FY 1987, each State would be allotted, from the amount appropriated, an amount bearing the same ratio to the amount appropriated as the number of persons in the State with end-stage renal disease in FY 1986 bears to the total number of such persons in the U.S. For FY 1988 and FY 1989, each State's allotment would be based on the total number of eligible patients as defined under the bill in the State as compared with the rest of the U.S. No State would receive less than $50,000 a year under the program. An eligible patient as defined by the bill would be an organ transplant patient who is not eligible to receive reimbursement for the total cost of immunosuppressive drug therapy under Medicare, Medicaid, or private insurance.

States would use their allotments under this block grant to provide immunosuppressive drug therapy for eligible patients by purchasing drugs and biologicals for such therapy and distributing them to transplant centers, by certifying that an individual is an eligible patient and reimbursing a transplant center for the costs of immunosuppressive drug therapy provided to such individual, or by any other method prescribed by the Secretary by regulation.

A State may require an eligible patient to make copayments for part of the costs of immunosuppressive drug therapy provided under this program.

A State may not use funds under this block grant to make direct payments to organ transplant patients, or to satisfy any requirements for the expenditure of non-Federal funds as a condition for the receipt of Federal funds. Not more than 10 percent of the allotment paid to a State may be used for costs of administration.

If a State does not submit an application for an allotment under this block grant or does not qualify for an allotment in a fiscal year, the Secretary would be authorized to use funds equal to the State's allotment for that year to provide immunosuppressive drug therapy to eligible patients in that State. Before providing such therapy in a State, the Secretary would be required to consult with the chief executive officer of the State and appropriate local officials. The Secretary would provide such therapy in the same ways that the State would under the block grant—by purchasing drugs and biologicals and distributing them to transplant centers, by certifying individuals as eligible patients and reimbursing transplant centers for the costs of immunosuppressive drug therapy provided such patients, or by any other method prescribed by the Secretary by regulation.

S. 2536 requires the Secretary to prepare and transmit to the Congress, within 24 months after the date of enactment, a report concerning the impact of this new block grant. The report would contain a description of the effect of the program on organ transplants in the U.S. and an analysis of the effects of the program on the costs of organ transplants and renal dialysis. The report would include an analysis of the extent to which funds paid to States under the block grant are used for purposes other than those specified under this legislation, including an analysis of the extent to which drugs and biologicals purchased under the block grant are provided to individuals who are not eligible patients as defined.

The report would also include appropriate recommendations, including recommendations as to whether the financial assistance under the block grant should be continued after FY 1989.

S. 2536 also amends section 1902(a)(10) of the Social Security Act (State Medicaid Plans) to insure that the making available of immunosuppressive drug therapy under this program to persons who have received organ transplants shall not require the making available of any other type of drug or the making available of any drugs for other individuals in the Medicaid program.

II. Background and Need for Legislation

The transplantation of organs in humans, especially kidneys, hearts, and livers, have become accepted and effective means of treating a significant number of patients with life-threatening organ failure. Since its beginning in the 1950s, organ transplantation has progressed steadily and, within the limitations of organs available for transplant, has become a realistic alternative for increasing numbers of patients.

A serious problem that affects organ transplantation is the gap between the need for organs and the supply of donors. Despite substantial support for transplantation and a general willingness on the part of the public to donate organs after death, the demand far exceeds the supply. At any one time, there an estimated 8,000 to 10,000 persons waiting for a donor organ to become available.

The 98th Congress responded to widespread public interest and involvement in and concern about the field of organ transplantation, particularly the shortage of organs and the cost of organ transplant procedures, by enactment of the National Organ Transplant Act of 1984 (P.L. 98–507). In addition to prohibiting the purchase of organs, the Act provided for the establishment of grants to organ procurement agencies and a national organ-sharing system. The 1984 act also established a 25-member Task Force on Organ Transplantation with membership representing medicine, law, theology, ethics, allied health, the health insurance industry, and the general public. Also represented were the Surgeon General of the Public Health Service, the National Institutes of Health, the Food and Drug Administration, and the Health Care Financing Administration.

The Task Force's mandate was to conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation. The Task Force was also asked to assess immunosuppressive medications used to prevent rejection and to report its findings, including recommendations on means of assuring that transplant patients who need such medications can obtain them.

The Task Force on Organ Transplantation issued its report on Immunosuppressive Therapies in October of 1985 and its final report on issues and recommendations concerning organ transplantation in April of 1986.

Transplantation and Immunosuppressive Drugs

As noted by the Task Force in its October 1985 report, one of the reasons for the rapid progress in recent years in the success of

organ transplantation has been the development of drugs to suppress the immune responses and thus control rejection of the transplanted organ. The immunosuppressive drug azothiaprine played a key role in making possible the extension of kidney transplants from those between twins only to other living related donors and unrelated donors. Corticosteroids, such as prednisone, were first used to reverse rejection episodes and subsequently were used in combination with other immunosuppressants. The introduction and use of cyclosporine as an immunosuppressant, following its licensing by the Food and Drug Administration in 1983, has been followed by sharp decreases in rates of failure for transplantation procedures. Based on current knowledge, according to the Task Force, it is apparent that, "except for kidney transplants involving identical twins, some form of lifetime immunosuppressive therapy must be provided to every transplant recipient in order to prevent rejection of the transplanted organ by the recipient's immune system."

Clinical transplantation of human organs began in the mid-1950s with transplantation of kidneys between twins. This was followed by transplantation of kidneys from living related donors and from cadaver donors unrelated to the recipients. In 1984, nearly 7,000 kidney transplants were performed in 170 transplant centers in the U.S. The one-year survival rate for patients was 92–95 percent. The survival rate for the graft itself, at one year, was 90 percent for living related donor grafts and between 70 and 80 percent for grafts from cadavers.

The first transplant of a human heart occurred in December 1967 in South Africa. The first heart transplant in the United States was performed shortly thereafter, in January 1968, at Stanford University in California. In 1984, there were 373 heart transplants performed in 37 centers with a one-year patient survival rate of 75–85 percent. According to the Task Force on Organ Transplantation in its April 1986 report, the unprecedented degree of activity in the field of human heart transplantation during the last two years has been due in part to the availability of cyclosporine therapy. The one-year survival rate for heart transplant recipients, prior to cyclosporine, was 65 percent; use of the drug has increased immediate survival by 10 to 15 percent.

Liver transplants are now performed much more extensively. In 1984, 308 liver transplants were performed in 25 centers. Before 1980, with azathioprine-steroid therapy, the reported five-year survival rate for 170 recipients of liver transplants was 18.2 percent. After 1980, using cyclosporine-steroid therapy, the projected five-year survival rate, based on 244 patients, had risen to 68 percent.

Transplantation of other organs such as pancreas and heart-lung are less common and less successful, and are still considered experimental.

INSURANCE COVERAGE FOR IMMUNOSUPPRESSIVE DRUGS

Paying for immunosuppressive drugs for transplant recipients remains a major obstacle in the use of such drugs and sometimes serves as a disincentive for patients to receive a transplant. The majority of private insurers and State Medicaid programs provide coverage for outpatient immunosuppressive drugs, that is, drugs

taken by the patient after leaving the hospital. Medicare does not provide coverage for outpatient self-administered drugs. The Task Force on Organ Transplantation in its October 1985 report stated that "the single most significant problem patients face in obtaining immunosuppressive medications is their inability to pay for the drugs (especially cyclosporine) because of the high cost of the drugs as well as inadequate or nonexistent insurance coverage." Costs for conventional immunosuppressive drugs (azothiaprine and prednisone), as taken by the patient after leaving the hospitaal, average from $1,000 to $2,000 per year. Cyclosporine which is becoming the immunosuppressive therapy of choice for many transplant patients, usually in combination with other conventional immunosuppressive medications, is significantly more expensive. The out-of-hospital cost of cyclosporine, self-administered by the patient, averages $5,000 for the first year of treatment following a transplant, depending on the treatment protocol used by the patient's transplant center and specific patient characteristics. Subsequent yearly costs may be less due to reduced dosages for long-term maintenance therapy, but it is clear that expenses of this magnitude verge on the catastrophic.

Medicare, through the End-Stage Renal Disease (ESRD) program, covers the cost of kidney transplantation, including the surgical cost of the transplant itself, as well as medications provided in-hospital and administered by the physician on an outpatient basis. Drugs self-administered by the patient, such as most outpatient immunosuppressive drugs, are not covered by Medicare.

Medicare has traditionally not covered any of the costs of heart or liver transplantation, because such procedures were considered to be experimental. In a news release on June 27, 1986, however, the Secretary of Health and Human Services, Dr. Otis R. Bowen, announced that Medicare will soon begin covering transplants in selected heart transplant facilities across the country. At the present time Medicare covers no outpatient self-administered drug costs.

Forty-three State Medicaid programs and the District of Columbia do provide outpatient drug coverage. Such coverage varies from State to State, but in general these States do provide outpatient drug coverage that includes payment for immunosuppressive medications.

The extent of private insurance coverage for outpatient immunosuppressive medications varies. Most Blue Cross/Blue Shield plans, commercial health insurers, and health maintenance organizations (HMOs) offer outpatient drug benefits which would cover immunosuppressive drugs, but not all members or policyholders elect to include such benefits in their health insurance policies.

In summarizing its evidence on insurance coverage, the April 1986 report of the Task Force on Organ Tranplantation estimated that, based on the number of insurance companies and plans, HMOs, and Government plans that offer outpatient drug benefits, roughly 58 million individuals (25 percent of the U.S. population) do not have any coverage for immunosuppressive medications. Due to the number of assumptions required in making this estimate, the Task Force states that this probably underestimates the number of persons without coverage for immunosuppressive drugs.

COST-EFFECTIVENESS OF IMMUNOSUPPRESSIVE DRUGS IN TRANSPLANTATION

When discussing the methods of paying for immunosuppressive drug therapy, one must consider the issue of cost-effectiveness of this therapy. The question of cost-effectiveness is especially difficult in considering transplantation as a treatment for end-stage diseases. In the case of end-stage renal disease, transplantation is not the only treatment option available to deal with the disease. Most end-stage renal disease patients can be maintained on several forms of kidney dialysis. The Task Force on Organ Transplantation states, however, that "the evidence is persuasive that kidney transplantation, when successful, is a less costly and more effective treatment modality than any form of renal dialysis."

The increasing cost of the Medicare ERSD program has made the question of cost-effectiveness a critical one. Current Medicare ERSD expenditures are estimated to be in excess of $2.3 billion for FY1985 for a patient population of 83,700 persons. Projections for 1991 show a patient population of 93,600, with total benefit payments exceeding $3.6 billion.

The estimated average cost of dialysis per patient is between $18,000 and $25,000, depending on whether the treatment is provided at home or in a dialysis center. The cost of transplantation using a cadaver kidney conventional immunosuppressive therapy was estimated by the Task Force to range between $25,000 and $35,000 in the first year following the transplantation, $6,000 the second year, $4,800 the third year, and $2,900 the fourth year. The cost of kidney transplants are even less if a living related donor is used, in part due to lower costs for immunosuppressive drugs. The Task Force analysis shows that the initial costs of transplantation are higher than those for dialysis. Within four years after a successful transplant operation, however, the costs of care for the patient have decreased significantly while the costs for the dialysis patient have remained constant. Overall, transplant patients with well-functioning transplants are significantly less costly to Medicare than those on dialysis.

In examining the recent use of cyclosporine in immunosuppressive therapy, the Task Force reports that both the duration of hospitalization as well as the accumulated charges in the first six months post-transplant are less for patients treated with cyclosporine than for those treated with conventional immunosuppressive therapy. This comparison did not reflect the charges for cyclosporine as an outpatient drug, which are high. The Task Force concluded, however, that even with the high cost of cyclosporine, its impact on the cost of cadaver renal transplantation was favorable. Because of its effect on controlling for graft failure, reduced rates of complications, and shorter lengths of hospital stay, cyclosporine was found to be at least cost-neutral in the first six months post-transplant. In addition, the patient benefits by having fewer complications than with conventional immunosuppressive therapy.

There is little information available on cost-effectivness of heart and liver transplantation. In addition, it is difficult to compare the costs of transplantation in such cases with the costs of the alternative, which frequently is extended hospital care prior to death.

Some level of medical care is provided to end-stage heart and liver patients, and some transplant surgeons, according to the Task Force, argue that the cost of a transplant is only slightly higher than the cost of treating the patient in the absence of a transplant. Moreover, it has been argued that the patient who receives a transplant has a reasonably high probability of surviving and returning to a productive life.

The Task Force cites several examples of the high cost of Medicare care for the dying patient. The routine care of a terminally ill cancer patient, for example, can exceed $50,000. The mean cost per patient year for caring for children with cancer was $29,708. Other studies cited show the impact of dying on Medicare expenditures. In 1978, 5.9 percent of Medicare beneficiaries who died accounted for 27.9 percent of all Medicare expenditures. The same study showed that 30 percent of all expenses of decedents occurred in the last 30 days of life, 46 percent in the last 60 days, and 77 percent in the last six months of life.

The Task Force concluded that while extrarenal transplantation is an expensive endeavor, it is clear that the alternative is not without cost, and that until, if ever, a legal and ethical basis is provided for routine non-treatment of patients with end-stage disease, physicians will continue to treat the dying patient in a vigorous manner.

III. History of Legislation

The Committee has a long-standing interest in and concern for the problems involved in organ transplantation. During the 98th Congress, the Committee held a series of hearings on the subject. These hearings, on October 20, 1983, in Washington and on May 25, 1984, in Oklahoma City, Oklahoma, examined the problems involved in obtaining organs for transplant surgery, and led to the enactment of P.L. 98-507, the Organ Transplant Act of 1984.

On June 10, 1986, Senator Hatch and Senator Kennedy introduced in the Senate a bill, S. 2536, the Immunosuppressive Drug Therapy Act of 1986. On June 11, the Committee held hearings on the bill and on the issue of who will pay for outpatient self-administered immunosuppressive drug therapy.

The Committee considered S. 2536 in executive session on 1986, and agreed to report it favorably to the Senate.

IV. Text of Bill as Reported

[Omit the part enclosed in black brackets and insert the part printed in italic]

A BILL To provide for block grants to States to pay the costs of immunosuppressive drugs for organ transplant patients

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Immunosuppressive Drug Therapy Act of 1986".

FINDINGS

Sec. 2. The Congress finds and declares that—

(1) new immunosuppressive drug therapies have made cadaver organ transplants increasingly successful;

(2) approximately 25 percent of individuals needing organ transplants have no private insurance coverage for immunosuppressive drugs and are not eligible for coverage for such drugs under the Medicaid program;

(3) the use of immunosuppressive drug therapy could result in savings in medical costs, since—

(A) the cost of hemodialysis is between $18,000 and $25,000 per patient per year;

(B) the cost of immunosuppressive drug therapy is between $5,000 and $7,000 per patient during the first year of therapy; and

(C) the cost of a successful renal transplant is between $25,000 and $35,000 per patient during the year in which the transplant is performed, $6,000 per patient during the first year after the year in which the transplant is performed, $4,800 per patient during the second year after the year in which the transplant is performed, and $2,900 per patient in the third year after the year in which the transplant is performed; and

(4) under the Medicaid program, 43 States and the District of Columbia provide coverage for immunosuppressive drug therapy.

ESTABLISHMENT OF BLOCK GRANT PROGRAM

SEC. 3. Title XIX of the Public Health Service Act is amended by adding at the end thereof the following new part:

"PART C—IMMUNOSUPPRESSIVE DRUG THERAPY BLOCK GRANT

"DEFINITIONS

"SEC. 1921. For purposes of this part—

"(1) the term 'eligible patient' means an organ transplant patient who is not eligible to receive reimbursement for the total cost of immunosuppressive drug therapy under title XVIII of the Social Security Act, under the State's medicaid plan under title XIX of such Act, or under private insurance;

"(2) the term 'immunosuppressive drug therapy' means drugs and biologicals which are to be used for the purpose of preventing the rejection of transplanted organs and tissues and which can be administered by the transplant patient; and

"(3) the term 'transplant center' means a transplant center certified by a State under the laws and regulations of such State.

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 1922. For the purpose of allotments to States to carry out this part, there are authorized to be appropriated $15,000,000 for each of the fiscal years 1987, 1988, and 1989.

"ALLOTMENTS

"SEC. 1923. (a)(1)(A) From amounts appropriated under section 1922 for [each of the fiscal years 1987 and 1988,] *fiscal year 1987,* the Secretary shall allot to each State an amount which bears the same ratio to the total amount appropriated under such section for such fiscal year as the number of individuals having end-stage renal disease in the State in [the immediately preceding] fiscal year *1986* bears to the total number of such individuals in the United States in such preceding fiscal year (as determined by the Secretary), except as provided in paragraph (2).

[(B) From amounts appropriated under section 1922 for fiscal year 1989, the Secretary shall allot to each State an amount which bears the same ratio to the total amount appropriated under such section for such fiscal year as the total number of eligible patients in the State bears to the total number of eligible patients in the United States.]

"(B) From amounts appropriated under section 1922 for each of the fiscal years 1988 and 1989, the Secretary shall allot to each State for each such fiscal year an amount which bears the same ratio to the total amount appropriated under such section for such fiscal year as the total number of eligible patients in the State bears to the total number of eligible patients in the United States, except as provided in paragraph (2).

"(2) Notwithstanding paragraph (1), the allotment of any State in any fiscal year under this subsection shall not be less than $50,000. If, under paragraph (1), the allotment of any State in any fiscal year will be less than $50,000, the Secretary shall increase the allotment of such State to $50,000 and shall proportionately reduce the allotments of all other States whose allotment exceeds $50,000 in a manner that will insure that the allotment of each State in such fiscal year is at least $50,000.

"(b) To the extent that all the funds appropriated under section 1922 for a fiscal year and available for allotment in such fiscal year are not otherwise allotted to States because—

"(1) one or more States have not submitted an application or description of activities in accordance with section 1926 for such fiscal year;

"(2) one or more States have notified the Secretary that they do not intend to use the full amount of their allotment; or

"(3) some State allotments are offset or repaid under section 1906(b)(3) (as such section applies to this part pursuant to section 1926(d));

such excess shall be allotted among each of the remaining States in proportion to the amount otherwise allotted to such States for such fiscal year without regard to this [subsection] *subsection, except as provided in section 1927.*

"PAYMENTS UNDER ALLOTMENTS TO STATES

"SEC. 1924. (a) For each fiscal year, the Secretary shall make payments, as provided by section 6503(a) of title 31, United States Code, to each State from its allotments under section 1923 from amounts appropriated for that fiscal year.

"(b) Any amount paid to a State for a fiscal year and remaining unobligated at the end of such year shall remain available for the next fiscal year to such State for the purposes for which it was made.

"USE OF ALLOTMENTS

"SEC. 1925. (a)(1) Except as provided in subsections (b) and (c), amounts paid to a State under section 1924 from its allotment under section 1923 for any fiscal year shall be used by the State to provide immunosuppressive drug therapy for eligible patients.

"(2) A State may use amounts paid to the State under section 1924 from its allotment under section 1923 to provide immunosuppressive drug therapy for eligible patients—

"(A) by purchasing the drugs and biologicals for such therapy and distributing such drugs and biologicals to transplant [centers or eligible patients] *centers;*

"(B) by certifying that an individual is an eligible patient for purposes of this part and by reimbursing a transplant center for the costs of immunosuppressive drug therapy provided by such center to such individual; *or*

"(C) by any other method prescribed by the Secretary by regulation (other than the method described in subsection (b)(1)).

"(3) A State may require an eligible patient to whom immunosuppressive drug therapy is provided with amounts paid to the State under this part to make copayments for part of the costs of such threapy, without regard to section 1916 of the Social Security Act.

"(b) A State may not use amounts paid to it under section 1924 to—

"(1) make direct payments to organ transplant patients; or

"(2) satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.

"(c) Not more than 10 percent of the total amount paid to any State under section 1924 from its allotment under section 1923 for any fiscal year may be used for administering the funds made available under section 1924. The State will pay from non-Federal sources the remaining costs of administering such funds.

"APPLICATION AND DESCRIPTION OF ACTIVITIES; REQUIREMENTS

"SEC. 1926. (a) In order to receive an allotment for a fiscal year under section 1923, each State shall submit an application to the Secretary. Each such application shall be in such form and submitted by such date as the Secretary shall require. Each such application shall contain assurances that the State will meet the requirements of subsection (b).

"(b) As part of the annual application required by subsection (a), the chief executive officer of each State shall—

"(1) certify that the State agrees to use the funds allotted to the State under section 1923 in accordance with the requirements of this part;

"(2) agrees to cooperate with Federal investigations undertaken in accordance with section 1907 (as such section applies to this part pursuant to subsection (d) of this section); and

"(3) certify that the State agrees that Federal funds made available under section 1924 for any period will be so used as to supplement and increase the level of State, local, and other non-Federal funds that would in the absence of such Federal funds be made available for the activities for which funds are provided under that section and will in no event supplant such State, local, and other non-Federal funds.

The Secretary may not prescribe for a State the manner of compliance with the requirements of this subsection.

"(c) The chief executive officer of a State shall, as part of the application required by subsection (a), also prepare and furnish the Secretary (in accordance with such form as the Secretary shall provide) with a description of the intended use of the payments the State will receive under section 1924 for the fiscal year for which the application is submitted, including information on the programs and activities to be supported. The description shall be made public within the State in such manner as to facilitate comment from any person (including any Federal or other public agency) during development of the description and after its transmittal. The description shall be revised (consistent with this section) throughout the year as may be necessary to reflect substantial changes in the programs and activities assisted by the State under this part, and any revision shall be subject to the requirements of the preceding sentence.

"(d) Except where inconsistent with the provisions of this part, the provisions of section 1903(b), section 1906(a), paragraphs (1) through (5) of section 1906(b), and sections 1907, 1908, and 1909 shall apply to this part in the same manner as such provisions apply to part A of this title.

"(e) Each annual report submitted by a State to the Secretary under section 1906(a) (as such section applies to this part pursuant to subsection (d) of this section) with respect to its activities under this part shall contain—

"(1) a specification of the number of eligible patients in the State receiving immunosuppressive drug therapy with amounts paid to the State under this part;

"(2) a description of the amount of any copayment required by the State under section 1925(a)(3); and

"(3) a certification that amounts paid to the State under this part are being used in accordance with the provisions of this [part.".] *Part.*

"IMMUNOSUPPRESSIVE DRUG THERAPY FOR PATIENTS IN STATES WHICH DO NOT APPLY FOR ALLOTMENTS

"SEC. 1927. (a) If a State does not submit an application for an allotment under section 1926 for a fiscal year or does not qualify for such an allotment for such fiscal year, the Secretary may use an amount which—

"(1) is from amounts appropriated under section 1922 for such fiscal year; and

"(2) is equal to the State's allotment under section 1923(a) for such fiscal year,

to provide immunosuppressive drug therapy to eligible patients in such State in accordance with subsection (b). Before providing such therapy in such State under this section, the Secretary shall consult with the Chief executive officer of the State and appropriate local officials.

"(b) Under subsection (a), the Secretary may provide immunosuppressive drug therapy to eligible patients in a State—

"(A) by purchasing the drugs and biologicals for such therapy and distributing such drugs and biologicals to transplant centers;

"(B) by certifying that an individual is an eligible patient for purposes of this part and by reimbursing a transplant center for the costs of immunosuppressive drug therapy provided by such center to such individual; or

"(C) by any other method prescribed by the Secretary by regulation (other than the method described in section 1925(b)(1).".

REPORT

SEC. 4. Within 24 months after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and transmit to the Congress a report concerning the impact of part C of title XIX of the Public Health Service Act (as added by section 3 of this Act). The report shall contain—

(1) a description of the effect of the program established under such part on organ transplants in the United States;

(2) an analysis of the effects of such program on the costs of organ transplants and renal dialysis;

(3) an analysis of the extent to which amounts paid to States under such part are used for purposes other than the purposes specified by such part, including an analysis of the extent to which drugs and biologicals purchased with such amounts are provided to individuals who are not eligible patients under such part; and

(4) such recommendations as the Secretary considers appropriate, including recommendations as to whether financial assistance under such program should be continued during fiscal years after fiscal year 1989.

MEDICAID PROVISION

SEC. 5. (a) Section 1902(a)(10) of the Social Security Act is amended in the matter following subparagraph (D)—

(1) by striking out "and" at the end of subclause (III) and inserting in lieu thereof a comma; and

(2) by inserting before the semicolon at the end thereof the following: ," and (V) the making available of immunosuppressive drug therapy (or immunosuppressive drugs) to individuals who have received organ transplants shall not, by reason of this paragraph (10), require the making available of any other type of drug or the making available of any drugs for other individuals".

(b) The amendments made by subsection (a) shall apply to drugs furnished after the date of the enactment of this Act.

V. Committee Views

The Labor and Human Resources Committee believes S. 2536 is timely, necessary, and essential for thousands of Americans needing organ transplants in order to survive or improve their quality of life. In 1984, approximately 8,000 Americans received organ transplants. This figure was approximately thirty-three percent higher than it was just two years ago, and the number is expected to grow.

The Federal Government currently covers both renal dialysis and kidney transplants through the End Stage Renal Disease (ESRD) program. This program is funded by the Medicare trust funds at a cost of more than $2.3 billion a year. The cost per year of renal dialysis is between $18,000 and $25,000 while a successful kidney transplant cost $25,000 to $35,000 the first year, $6,000 the second year, $4,800 the third year, and $2,900 the fourth year. This represents a potential savings to the federal government of $30,000 to $60,000 over a five year period from a successful transplant. In addition, the cost of kidney transplantation has continued to decline.

All victims of end-stage renal disease are eligible for Medicare coverage by virtue of their disease. In addition, Medicare will cover heart transplants for patients eligible for Medicare by reason of age or disability status and liver transplants for those few children who are Medicare eligible. Coverage is also provided through Medicaid for liver transplants in 33 states and heart transplants in 25 states. Other transplant patients rely on private insurance, personal assets, or other non-Government resources to finance the cost of transplant operations.

Of the approximately 8000 patients receiving transplants annually, an estimated one quarter have no insurance coverage for the immunosuppressive drugs needed to successfully sustain the transplant. Such drugs are extremely costly. The cost of the most effective immunosuppressive drug, cyclosporine, averages $5,000 per year for a typical transplant patient. In most cases, if the patient cannot afford the immunosuppressive drugs, the patient is not considered a candidate for the transplant. In some cases, patients are transplanted, but must rely on less effective, cheaper drugs that can increase the rejection rate as much as 50 percent. This problem will undoubtedly increase now that the federal government has determined that heart transplants are no longer experimental.

Currently, the federal government divides drugs into three categories for reimbursement purposes under Medicare. Under Medicare Part A, drugs which are received in a hospital are covered in the same manner as other hospital services. Patients pay a deductible on entering the hospital and must also pay copayments for very long stays. Under Medicare Part B, drugs which are received outside the hospital setting, but administered by a health care provider, are covered at 80 percent of the Medicare reasonable charge, with the patient paying the other 20 percent.

The third group of drugs are those which are administered outside of the hospital without the help of a health care provider. This group is commonly referred to as self-administered drugs, and pa-

tients pay the full cost of those drugs. It is at that this group of drugs that the Committee's legislation is directed.

The Committee recognizes that there is newly developed immunosuppressive therapy recently receiving FDA approval for treatment of acute renal transplant rejection. Products of this type are currently entitled to reimbursement under Medicare Parts A and B because they require professional administration. Nonetheless, new products such as this may present reimbursement concerns due to their relatively high cost, because the patient is required to pay a certain portion of medical coverage through copayments and deductibles. This may shift incentives toward less desirable and possibly less cost effective therapeutic alternatives. Those potential reimbursement problems are not addressed in this legislation but may need attention in the near future. The Committee encourages further examination of those issues to determine whether additional action is necessary, through regulation or legislation. The committee is interested in assuring adequate coverage for immunosuppressive therapy regardless of the treatment setting.

In addition, the Committee encourages a continuing review of the reimbursement situation in the context of State Medicaid programs. To guarantee safe and effective treatment of acute transplant rejection it may be necessary to alter Medicaid policies and practices to some extent in order to mitigate the effects of high copayment burdens.

While this legislation is earmarked to assist with the health care cost of specific type of illness, the Committee feels that this legislation is markedly different from the Black Lung and End Stage Renal Disease programs which it has been compared to. First, this legislation authorizes a fixed sum instead of being open-ended like those programs. Second, unlike other programs which have no potential of saving money, this program has the real potential of reducing federal outlays because organ transplantation may be less costly than more traditional forms of medical care such as renal dialysis or extended hospital stays in intensive care units. Third, instead of providing first-dollar coverage, funding under this legislation is only available when the patient has another funding source for the transplant operation itself. Lastly, this program does not provide full coverage to all patients with the medical condition. Instead, the extent of assistance may be based on the individuals ability to pay.

This legislation authorizes $15 million a year, for three years, in the form of a grant to States for the purpose of purchasing self-administered drugs. All organ transplant patients whose immunosuppressive drugs are not fully covered by existing private or public programs are eligible for assistance under this grant program, though the extent of assistance may be based on the individuals ability to pay. The Committee is aware that the President is currently considering proposals for a comprehensive catastrophic insurance program which would assure financing for the cost of all expensive health services. If such proposals are enacted, they may eliminate the need for the program established by this legislation. The committee will determine whether to continue the program at that time.

States have two options for administering the immunosuppressive drug funding program. They may purchase the drugs, and make them available to transplant centers for distribution to patients which the State has certified as eligible or the States may certify patients as eligible and then reimburse the transplant centers for the cost of drugs provided these patients. In addition, if a State has a compelling reason to administer this program in a different manner, it may do so if approved by the Secretary.

The legislation does not prevent States from requiring patients to pay part of the cost of their immunosuppressive drugs provided under this program. The Committee anticipates that any program of co-payments established by the State will be carefully designed to reflect individual patients' ability to make out-of-pocket payments.

Since this legislation was designed, and the authorization level established to fill gaps in funding from Federal, State, and private sources, it includes a requirement that funds provided under this Act shall not supplant State, local and other non-Federal funds. Reduction in current State programs to fund immunosuppressive drugs would be a basis for denial of participation in the grant program.

The Committee recognizes that organ transportation is a rapidly changing field. It has required the Secretary to report to the Congress, within 24 months after enactment of the legislation, on its implementation and effects on the cost, patient selection, and number of organs transplanted. This report, along with the required Secretarial recommendation, will assist the Committee in determining whether to modify, terminate, or extend the program after fiscal year 1989.

VI. Votes In Committee

S. 2536 was ordered reported favorably by the Labor and Human Resources Committee by a voice vote.

VII. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, August 4, 1986.

Hon. Orrin G. Hatch,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the attached cost estimate for S. 2536, the Immunosuppressive Drug Therapy Act of 1986, as ordered reported by the Senate Committee on Labor and Human Resources on June 25, 1986.

Should you so desire, we would be pleased to provide further details on the attached cost estimate. Please contact me or have your staff contact Marianne Deignan (226–2820).

With best wishes,

Sincerely,

Rudolph G. Penner, *Director.*

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 2536.

2. Bill title: Immunosuppressive Drug Therapy Act of 1986.

3. Bill status: As ordered reported by the Committee on Labor and Human Resources on June 25, 1986.

4. Bill purpose: To provide for block grants to states to pay the costs of immunosuppressive drugs for eligible Medicare organ transplant patients.

5. Estimated cost to the Federal Government:

[By fiscal year, in millions of dollars]

	1987	1988	1989	1990	1991
Immunosuppressive drug therapy block grant:					
Authorization level	15	15	15		
Estimated outlays	15	15	15	0	0

The effects of this bill would fall in budget function 550.

Basis of Estimate

Immunosuppressive Drug Therapy Block Grant.—Section 3 amends the Public Health Service Act to authorize the Immunosuppressive Drug Therapy Block Grant Program. For fiscal years 1987, 1988 and 1989 there is authorized to be appropriated $15 million in each fiscal year to provide states with funds to pay the total cost of immunosuppressive therapy for eligible Medicare transplant patients. From the amounts appropriated, the Secretary of Health and Human Services would allot an amount to each state in proportion to the number of eligible transplant recipients in each state. An eligible transplant recipient is a patient who currently has no federal or private insurance coverage for immunosuppressive drug therapy.

6. Estimated cost to State and local government: States would be required to administer the block grant. State budgets would only be affected if the cost of administering the program exceeded the ten percent of the allotment authorized to be spent on administration of the program.

7. Estimate comparison: None.

8. Previous CBO estimate: In previous years CBO has produced estimates for Medicare coverage of cyclosporine that included savings to Medicare for reduced hospital and other costs due to the increased use of cyclosporine. Recent evidence shows that virtually all transplant patients are currently receiving cyclosporine for at least some time after a transplant and therefore CBO now estimates that any savings offsets to Medicare for coverage of cyclosporine would be insignificant.

9. Estimate prepared by: Marianne Deignan.

10. Estimate approved by: C.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

VIII. Regulatory Impact Statement

The Committee has determined that there will be a modest increase in regulatory burden and paperwork. The States will have to provide the Secretary of Health and Human Services with an annual report of the number of patients in the State who are eligible for this program, and the method used to calculate copayments. The State is also required to establish a mechanism to certify patients; however, this will probably be through existing mechanisms.

The Secretary is required to annually calculate the allotments for each State to submit a report to Congress after the second year of the authorization.

IX. Family Fairness Statement

The Committee has determined that this legislation will have a positive impact on families. There is frequently a substantial financial burden when a family member receives an organ transplant. This financial burden affects the family both economically and emotionally. This legislation relieves some of that financial burden.

X. Section-by-Section Analysis

The bill provides that the Act may be cited as the "Immunosuppressive Drug Therapy Act of 1986."

Section 2 of the bill states the findings of the Congress regarding immunosuppressive drug therapy.

Section 3 of the bill amends title XIX of the Public Health Service (PHS) Act by adding a new part C—Immunosuppressive Drug Therapy Block Grant.

Under the new part C, a new section 1921 of the PHS Act defines three terms used in the legislation:

(1) the term "eligible patient" means an organ transplant patient who is not eligible to receive reimbursement for the total cost of immunosuppressive drug therapy under Medicare, Medicaid, or private insurance;

(2) "immunosuppressive drug therapy" means drugs and biologicals used to prevent the rejection of transplanted organs and tissues and administered by the transplant patient; and

(3) "transplant center" means a transplant center certified by a State under its laws and regulations.

The new section 1922 authorizes appropriations of $15 million for each of the fiscal years 1987 through 1989 for allotments to States under the new part C.

The new section 1923(a) directs the Secretary to allot to each State, from the amount appropriated under section 1922 for FY 1987, an amount bearing the same ratio to the total amount appropriated as the number of individuals with end-state renal disease in the State in FY 1986 bears to the total number of such individuals in the U.S. that year.

For fiscal years 1988 and 1989, the allotment to each State will bear the same ratio to the amount appropriated as the number of eligible patients in the State bears to the number of eligible patients in the U.S.

The total allotment of any State under this section shall not be less than $50,000 a year. If, under the allotment formula prescribed in this section, the allotment of any State would be less than $50,000, the Secretary is directed to increase the allotment of such State to $50,000 and proportionately reduce the allotments of all other States whose allotments exceed $50,000 in a manner that insures that the allotment of each State is at least $50,000.

Subsection (b) of the new section 1923 provides for the reallotment of any funds appropriated for a fiscal year and available for allotment in that year which are not allotted for any of the following reasons:

(1) one or more States have not submitted an application or description of activities in accordance with section 1926 below for such fiscal year;

(2) one or more States have notified the Secretary that they do not intend to use the full amount of their allotment; or

(3) some State allotments are offset or repaid under section 1906(b)(3) of the PHS Act as it applies to this part pursuant to section 1926(d) below. This subsection provides that any such excess shall be allotted among each of the remaining States in proportion to the amount otherwise allotted to those States for this fiscal year, except as provided in section 1927 below.

The new section 1924 directs the Secretary to make payments, for each fiscal year, as provided by section 6503(a), title 31, United States Code, to each State from its allotments under section 1923 from amounts appropriated for that year. Any amount paid to a State for a fiscal year and remaining unobligated at the end of the year shall remain available to the State for the next fiscal year.

The new section 1925 provides that States shall use allotments under this part to provide immunosuppressive drug therapy for eligible patients—

(A) by purchasing the drugs and biologicals for such therapy and distributing them to transplant centers;

(B) by certifying that an individual is an eligible patient for purposes of this part and by reimbursing a transplant center for the costs of immunosuppressive drug therapy provided by such center to such individual; or

(C) by any other method prescribed by the Secretary by regulation.

A State may require an eligible patient to whom immunosuppressive drug therapy is provided under this part to make copayments for part of the costs of such therapy, without regard to section 1916 of the Social Security Act (Use of Enrollment Fees, Premiums, Deductions, Cost Sharing, and Similar Charges).

A State may not use funds under this part to make direct payments to organ transplant patients or to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds. Not more than 10 percent of the amount allotted to a State under this part for a fiscal year may be used to administer the funds available. The State will pay from non-Federal sources the remaining costs of administration.

Section 1926(a) requires a State, in order to receive an allotment under section 1923, to submit an application to the Secretary. Each application shall be in such form and submitted by such date as re-

quired by the Secretary and contain assurances that the State will meet certain requirements, as described below.

Section 1926(b) provides that, as part of the annual application, the chief executive of each State is required to—

(1) certify that the State agrees to use funds under section 1923 in accordance with the requirements of this part;

(2) agree to cooperate with Federal investigations undertaken in accordance with section 1907 of the PHS Act; and

(3) certify that the State agrees that Federal funds made available under section 1924 will be so used as to supplement and increase the level of State, local, and other non-Federal funds that would in the absence of such Federal funds be made available for activities for which funds are provided under that section and will in no event supplant such State, local, and other non-Federal funds. The Secretary may not prescribe for a State the manner of compliance with these requirements.

Section 1926(c) requires the chief executive of a State, as part of the required application, to prepare and furnish the Secretary with a description of the intended use of funds received under this part, including information on programs and activities to be supported. The description must be made public in the State in such a manner as to facilitate comment during development of the description and after its transmittal. The description shall be revised throughout the year as may be necessary to reflect substantial changes in programs and activities assisted by the State under this part.

Section 1926(d) provides that, except where inconsistent with provisions of this part, the provisions of certain sections in part A of title XIX shall apply to this part in the same manner as they apply to part A. These other sections include section 1903(b), section 1906(a), paragraphs (1) through (5) of section 1906(b), and sections 1907, 1908, and 1909.

Section 1926(e) requires that each annual report submitted by a State to the Secretary under section 1906(a) (as it applies to this part) with respect to its activities under this part shall contain—

(1) a specification of the number of eligible patients in the State receiving immunosuppressive drug therapy with amounts paid to the State under this part;

(2) a description of the amount of any copayment required by the State under section 1925, and

(3) a certification that amounts paid to the State under this part are being used in accordance with the provisions of this part.

The new section 1927 provides that if a State does not submit an application for an allotment under this part for a fiscal year or does not qualify for such an allotment for that year, the Secretary may use funds from those appropriated under this part and equal to the State's allotment for that year to provide immunosuppressive drug therapy to eligible patients in the State. Before providing such therapy under this section, the Secretary is required to consult with the chief executive officer of the State and appropriate local officials.

The Secretary may provide immunosuppressive drug therapy to eligible patients in a State—

(A) by purchasing the drugs and biologicals for such therapy and distributing them to transplant centers;

(B) by certifying an individual as an eligible patient and reimbursing a transplant center for the costs of immunosuppressive drug therapy provided by the center to such individual; or

(C) by any other method prescribed by the Secretary by regulation.

Section 4 of the bill requires the Secretary, within 24 months after the date of enactment of this bill, to prepare and transmit to the Congress a report concerning the impact of the new part C of title XIX of the PHS Act. The report shall contain—

(1) a description of the effect of the program established under part C on organ transplants in the U.S.;

(2) an analysis of the effects of such program on the costs of organ transplants and renal dialysis;

(3) an analysis of the extent to which amounts paid to States under part C are used for purposes other than the purposes specified by such part, including an analysis of the extent to which drugs and biologicals purchased with such amounts are provided to individuals who are not eligible patients under such part; and

(4) such recommendations as the Secretary considers appropriate, including recommendations as to whether financial assistance under such program should be continued after FY 1989.

Section 5 of the bill amends section 1902(a)(10) of the Social Security Act (State Medicaid Plans) to provide that the making available of immunosuppressive drug therapy (or immunosuppressive drugs) to individuals who have received organ transplants shall not, by reason of this provision, require the making available of any other type of drug or the making available of any drugs for other individuals. This provision would apply to drugs furnished after the date of enactment.

XI. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended, or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Health Service Act

* * * * * * *

Title XIX—Block Grants

* * * * * * *

Part C—Immunosuppressive Drug Therapy Block Grant

DEFINITIONS

Sec. 1921. For purposes of this part—

(1) the term "eligible patient" means an organ transplant patient who is not eligible to receive reimbursement for the total cost of immunosuppressive drug therapy under title XVIII of the Social Security Act, under the State's medicaid plan under title XIX of such Act, or under private insurance;

(2) the term "immunosuppressive drug therapy" means drugs and biologicals which are to be used for the purpose of preventing the rejection of transplanted organs and tissues and which can be administered by the transplant patient; and

(2) the term "transplant center" means a transplant center verified by a State under the laws and regulations of such State.

AUTHORIZATION OF APPROPRIATIONS

SEC. 1922. For the purposes of allotments to States to carry out this part, there are authorized to be appropriated $15,000,000 for each of the fiscal years 1987, 1988, and 1989.

ALLOTMENTS

SEC. 1923. (a)(1)(A) From amounts appropriated under section 1922 for fiscal year 1987, the Secretary shall allot to each State an amount which bears the same ratio to the total amount appropriated under such section for such fiscal year as the number of individuals having end-stage renal disease in the State in fiscal year 1986 bears to the total number of such individuals in the United States in such fiscal year (as determined by the Secretary), except as provided in paragraph (2).

(B) From amounts appropriated under section 1922 for each of the fiscal years 1988 and 1989, the Secretary shall allot to each State for each such fiscal year an amount which bears the same ratio to the total amount appropriated under such section for such fiscal year as the total number of eligible patients in the State bears to the total number of eligible patients in the United States, except as provided in paragraph (2).

(2) Notwithstanding paragraph (1), the allotment of any State in any fiscal year under this subsection shall not be less than $50,000. If, under paragraph (1), the allotment of any State in any fiscal year will be less than $50,000, the Secretary shall increase the allotment of such State to $50,000 and shall proportionately reduce the allotments of all other States whose allotment exceeds $50,000 in a manner that will insure that the allotment of each State in such fiscal year is at least $50,000.

(b) To the extent that all the funds appropriated under section 1922 for a fiscal year and available for allotment in such fiscal year are not otherwise allotted to States because—

(1) one or more States have not submitted an application or description of activities in accordance with section 1926 for such fiscal year;

(2) one or more States have notified the Secretary that they do not intend to use the full amount of their allotment; or

(3) some State allotments are offset or repaid under section 1906(b)(3) (as such section applies to this part pursuant to section 1926(d));

such excess shall be allotted among each of the remaining States in proportion to the amount otherwise allotted to such States for such fiscal year without regard to this subsection, except as provided in section 1927.

PAYMENTS UNDER ALLOTMENTS TO STATES

SEC. 1924. (a) For each fiscal year, the Secretary shall make payments, as provided by section 6503(a) of title 31, United States Code, to each State from its allotments under section 1923 from amounts appropriated for that fiscal year.

(b) Any amount paid to a State for a fiscal year and remaining unobligated at the end of such year shall remain available for the next fiscal year to such State for the purposes for which it was made.

USE OF ALLOTMENTS

SEC. 1925. (a)(1) Except as provided in subsections (b) and (c), amounts paid to a State under section 1924 from its allotment under section 1923 for any fiscal year shall be used by the State to provide immunosuppressive drug therapy for eligible patients.

(2) A State may use amounts paid to the State under section 1924 from its allotment under section 1923 to provide immunosuppressive drug therapy for eligible patients—

(A) by purchasing the drugs and biologicals for such therapy and distributing such drugs and biologicals to transplant centers;

(B) by certifying that an individual is an eligible patient for purposes of this part and by reimbursing a transplant center for the costs of immunosuppressive drug therapy provided by such center to such individual; or

(C) by any other method prescribed by the Secretary by regulation (other than the method described in subsection (b)(1)).

(3) A State may require an eligible patient to whom immunosuppressive drug therapy is provided with amounts paid to the State under this part to make copayments for part of the costs of such therapy, without regard to section 1916 of the Social Security Act.

(b) A State may not use amounts paid to it under section 1924 to—

(1) make direct payments to organ transplant patients; or

(2) satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.

(c) Not more than 10 percent of the total amount paid to any State under section 1924 from its allotment under section 1923 for any fiscal year may be used for administering the funds made available under section 1924. The State will pay from non-Federal sources the remaining costs of administering such funds.

APPLICATION AND DESCRIPTION OF ACTIVITIES; REQUIREMENTS

SEC. 1926. (a) In order to receive an allotment for a fiscal year under section 1923, each State shall submit an application to the Secretary. Each such application shall be in such form and submitted by such date as the Secretary shall require. Each such applica-

tion shall contain assurances that the State will meet the requirements of subsection (b).

(b) As part of the annual application required by subsection (a), the chief executive officer of each State shall—

(1) certify that the State agrees to use the funds allotted to the State under section 1923 in accordance with the requirements of this part;

(2) agrees to cooperate with Federal investigations undertaken in accordance with section 1907 (as such section applies to this part pursuant to subsection (d) of this section); and

(3) certify that the State agrees that Federal funds made available under section 1924 for any period will be so used as to supplement and increase the level of State, local, and other non-Federal funds that would in the absence of such Federal funds be made available for the activities for which funds are provided under that section and will in no event supplant such State, local, and other non-Federal funds.

The Secretary may not prescribe for a State the manner of compliance with the requirements of this subsection.

(c) The chief executive officer of a State shall, as part of the application required by subsection (a), also prepare and furnish the Secretary (in accordance with such form as the Secretary shall provide) with a description of the intended use of the payments the State will receive under section 1924 for the fiscal year for which the application is submitted, including information on the programs and activities to be supported. The description shall be made public within the State in such manner as to facilitate comment from any person (including any Federal or other public agency) during development of the description and after its transmittal. The description shall be revised (consistent with this section) throughout the year as may be necessary to reflect substantial changes in the programs and activities assisted by the State under this part, and any revision shall be subject to the requirements of the preceding sentence.

(d) Except where inconsistent with the provisions of this part, the provisions of section 1903(b), section 1906(a), paragraphs (1) through (5) of section 1906(b), and sections 1907, 1908, and 1909 shall apply to this part in the same manner as such provisions apply to part A of this title.

(e) Each annual report submitted by a State to the Secretary under section 1906(a) (as such section applies to this part pursuant to subsection (d) of this section) with respect to its activities under this part shall contain—

(1) a specification of the number of eligible patients in the State receiving immunosuppressive drug therapy with amounts paid to the State under this part;

(2) a description of the amount of any copayment required by the State under section 1925(a)(3); and

(3) a certification that amounts paid to the State under this part are being used in accordance with the provisions of this part.

IMMUNOSUPPRESSIVE DRUG THERAPY FOR PATIENTS IN STATES WHICH DO NOT APPLY FOR ALLOTMENTS

SEC. 1927. (a) If a State does not submit an application for an allotment under section 1926 for a fiscal year or does not qualify for such an allotment for such fiscal year, the Secretary may use an amount which—

(1) is from amounts appropriated under section 1922 for such fiscal year; and

(2) is equal to the State's allotment under section 1923(a) for such fiscal year,

to provide immunosuppressive drug therapy to eligible patients in such State in accordance with subsection (b). Before providing such therapy in such State under this section, the Secretary shall consult with the chief executive officer of the State and appropriate local officials.

(b) Under subsection (a), the Secretary may provide immunosuppressive drug therapy to eligible patients in a State—

(A) by purchasing the drugs and biologicals for such therapy and distributing such drugs and biologicals to transplant centers;

(B) by certifying that an individual is an eligible patient for purposes of this part and by reimbursing a transplant center for the costs of immunosuppressive drug therapy provided by such center to such individual; or

(C) by any other method prescribed by the Secretary by regulation (other than the method described in section 1925(b)(1)).

Other Acts Affected by this Legislation

SOCIAL SECURITY ACT

* * * * * * *

TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

* * * * * * *

STATE PLANS FOR MEDICAL ASSISTANCE

SEC. 1902. (a) A State plan for medical assistance must—

(1) provide that it shall be in effect in all political subdivisions of the State, and, if administered by them, be mandatory upon them;

(2) provide for financial participation by the State equal to not less than 40 per centum of the non-Federal share of the expenditures under the plan with respect to which payments under section 1903 are authorized by this title; and, effective July 1, 1969, provide for financial participation by the State equal to all of such non-Federal share or provide for distribution of funds from Federal or State sources, for carrying out the State plan, on an equalization or other basis which will assure that the lack of adequate funds from local sources will

not result in lowering the amount, duration, scope, or quality of care and services available under the plan;

(3) provide for granting an opportunity for a fair hearing before the State agency to pay individual whose claim for medical assistance under the plan is denied or is not acted upon with reasonable promptness;

(4) provide (A) such methods of administration (including methods relating to the establishment and maintenance of personnel standards on a merit basis, except that the Secretary shall exercise no authority with respect to the selection, tenure of office, and compensation of any individual employed in accordance with such methods, and including provision for utilization of professional medical personnel in the administration and, where administered locally, supervision of administration of the plan) as are found by the Secretary to be necessary for the proper and efficient operation of the plan, (B) for the training and effective use of paid subprofessional staff, with particular emphasis on the full-time or part-time employment of recipients and other persons of low income, as community service aides, in the administration of the plan and for the use of nonpaid or partially paid volunteers in a social service volunteer program in providing services to applicants and recipients and in assisting any advisory committees established by the State agency, and (C) that each State or local officer of employee who is responsible for the expenditure of substantial amounts of funds under the State plan, each individual who formerly was such an officer or employee, and each partner of such officer or employee shall be prohibited from committing any act, in relation to any activity under the plan, the commission of which, in connection with any activity concerning the United States Government, by an officer or employee of the United States Government, an individual who was such an officer or employee, or a partner of such an officer or employee is prohibited by section 207 or 208 of title 18, United States Code;

(5) either provide for the establishment or designation of a single State agency to administer or to supervise the administration of the plan; or provide for the establishment or designation of a single State agency to administer or to supervise the administration of the plan, except that the determination of eligibility for medical assistance under the plan shall be made by the State or local agency administering the State plan approved under title I or XVI (insofar as it relates to the aged) if the State is eligible to participate in the State plan program established under title XVI, or by the agency or agencies administering the supplemental security income program established under title XVI or the State plan approved under part A of title IV if the State is not eligible to participate in the State plan program established under title XVI.

(6) provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time require, and comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports;

(7) provide safeguards which restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan;

(8) provide that all individuals wishing to make application for medical assistance under the plan shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals;

(9) provide—

(A) that the State health agency, or other appropriate State medical agency (whichever is utilized by the Secretary for the purpose specified in the first sentence of section 1864(a)), shall be responsible for establishing and maintaining health standards for private or public institutions in which recipients of medical assistance under the plan may receive care or services,

(B) for the establishment or designation of a State authority or authorities which shall be responsible for establishing and maintaining standards, other than those relating to health, for such institutions, and

(C) that any laboratory service paid for under such plan must be provided by a laboratory which meets the applicable requirements of section 1861(e)(9) or paragraphs (11) and (12) of section 1861(s), or, in the case of a laboratory which is in a rural health clinic, of section 1861(aa)(2)(G);

(10) provide—

(A) for making medical assistance available, including at least the care and services listed in paragraphs (1) through (5) and (17) of section 1905(a), to—

(i) all individuals—

(I) who are receiving aid or assistance under any plan of the State approved under title I, X, XIV, or XVI, or part A or part E of title IV (including individuals eligible under this title by reason of section 402(a)(37) or 406(h), or considered by the State to be receiving such aid as authorized under section 414(g)),

(II) with respect to whom supplemental security income benefits are being paid under title XVI, or

(III) who are qualified pregnant women or children as defined in section 1905(n);

(ii) at the option of the State, to any group or groups of individuals described in section 1905(a) (or, in the case of individuals described in section 1905(a)(i), to any reasonable categories of such individuals) who are not individuals described in clause (i) of this subparagraph but—

(I) who meet the income and resources requirements of the appropriate State plan described in clause (i) or the supplemental security income program (as the case may be),

(II) who would meet the income and resources requirements of the appropriate State plan described in clause (i) if their work-related child care

costs were paid from their earnings rather than by a State agency as a service expenditure,

(III) who would be eligible to receive aid under the appropriate State plan described in clause (i) if coverage under such plan was as broad as allowed under Federal law,

(IV) with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them, aid or assistance under the appropriate State plan described in clause (i), supplemental security income benefits under title XVI, or a State supplementary payment;

(V) who are in a medical institution, who meet the resource requirements of the appropriate State plan described in clause (i) or the supplemental security income program, and whose income does not exceed a separate income standard established by the State which is consistent with the limit established under section 1903(f)(4)(C), or

(VI) who would be eligible under the State plan under this title if they were in a medical institution, with respect to whom there has been a determination that but for the provision of home or community-based services described in section 1915(c) they would require the level of care provided in a hospital, skilled nursing facility or intermediate care facility the cost of which could be reimbursed under the State plan, and who will receive home or community-based services pursuant to a waiver granted by the Secretary under section 1915(c);

(B) that the medical assistance made available to any individual described in subparagraph (A)—

(i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual, and

(ii) shall not be less in amount, duration, or scope than the medical assistance made available to individuals not described in subparagraph (A);

(C) that if medical assistance is included for any group of individuals described in section 1905(a) who are not described in subparagraph (A), then—

(i) the plan must include a description of (I) the criteria for determining eligibility of individuals in the group for such medical assistance, (II) the amount, duration, and scope of medical assistance made available to individuals in the group, and (III) the single standard to be employed in determining income and resource eligibility for all such groups, and the methodology to be employed in determining such eligibility, which shall be the same methodology which would be employed under the supplemental security income

program in the case of groups consisting of aged, blind, or disabled individuals in a State in which such program is in effect, and which shall be the same methodology which would be employed under the appropriate State plan (described in subparagraph (A)(i)) to which such group is most closely categorically related in the case of other groups;

(ii) the plan must make available assistance—

(I) to individuals under the age of 18 who (but for income and resources) would be eligible for medical assistance as an individual described in subparagraph (A)(i), and

(II) to pregnant women, during the course of their pregnancy, who (but for income and resources) would be eligible for medical assistance as an individual described in subparagraph (A);

(iii) such medical assistance must include (I) with respect to children under 18 and individuals entitled to institutional services, ambulatory services, and (II) with respect to pregnant women, prenatal care and delivery services; and

(iv) if such medical assistance includes services in institutions for mental diseases or intermediate care facility services for the mentally retarded (or both) for any such group, it also must include for all groups covered at least the care and services listed in paragraphs (1) through (5) and (17) of section 1905(a) or the care and services listed in any 7 of the paragraphs numbered (1) through (17) of such section; and

(D) for the inclusion of home health services for any individual who, under the State plan, is entitled to skilled nursing facility services;

except that (I) the making available of the services described in paragraph (4), (14), or (16) of section 1905(a) to individuals meeting the age requirements prescribed therein shall not, by reason of this paragraph (10), require the making available of any such services, or the making available of such services of the same amount, duration, and scope, to individuals of any other ages, (II) the making available of supplementary medical insurance benefits under part B of title XVIII to individuals eligible therefor (either pursuant to an agreement entered into under section 1843 or by reason of the payment of premiums under such title by the State agency on behalf of such individuals), or provision for meeting part or all of the cost of deductibles, cost sharing, or similar charges under part B of title XVIII for individuals eligible for benefits under such part, shall not, by reason of this paragraph (10), require the making available of any such benefits, or the making available of services of the same amount, duration, and scope, to any other individuals, (III) the making available of medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in clause (A) to any classification of individuals approved by the Secretary with respect to whom there is being paid, or who are eligible, or would

be eligible if they were not in a medical institution, to have paid with respect to them, a State supplementary payment shall not, by reason of this paragraph (10), require the making available of any such assistance, or the making available of such assistance of the same amount, duration, and scope, to any other individuals not described in clause (A) [and], (IV) the imposition of a deductible, cost sharing, or similar charge for any item or service furnished to an individual not eligible for the exemption under section 1916(a)(2) or (b)(2) shall not require the imposition of a deductible, cost sharing, or similar charge for the same item or service furnished to an individual who is eligible for such exemption, *and (V) the making available of immunosuppressive drug therapy (or immunosuppressive drugs) to individuals who have received organ transplants shall not, by reason of this paragraph (10), require the making available of any other type of drug or the making available of any drugs for other individuals*;

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XII. ADDITIONAL VIEWS OF MR. QUAYLE

I must reluctantly express my views against this bill which provides for Federal funding of immunosuppressive drugs. Rapid advances in medical technology have led to serious questions of economics and equity. These questions are exemplified by the issues surrounding organ transplantation and in the bill which this Committee has—unwisely in my view—decided to approve. As legislators, we cannot consider issues such as organ transplantation and related matters in isolation from other significant health problems that compete for our limited resources.

While I sympathize with those individuals who require immunosuppressive drugs, I am unable to support this legislation because I believe it represents unsound Federal health policy which will initiate a precedent that Congress will find almost impossible to deal with in a rational fashion.

Currently, out-patient drugs may be paid for, at the option of the States under the Medicaid Program; the Federal government does not pay for any self-administered, out-patient drugs under the Medicare Program. Further, the Federal government does not pay any part of the medical bills for individuals just because those bills are not covered by insurance, if the individual does not qualify for the Medicare or Medicaid Programs—and many such individuals incur costs equal to or higher than those of transplant patients.

This legislation selects one specific illness and one set of therapeutic agents which are politically attractive for special treatment. In my view, this raises a serious question of equity. I cannot justify singling out immunosuppressive drugs when there are other expensive drugs needed by many individuals with life-threatening illnesses. I think we need to ask why establishing a grant program to pay for the drugs needed by transplant patients is more worthwhile than paying for the multitude of costly hypertensive and cancer drugs a Medicare patient may need to sustain his or her life? The proponents of this bill offer no rational explanation of why the government should pay the bills for immunosuppressive drugs rather than those of otherwise equally worthy claimants.

S. 2536 establishes a policy that the Federal government will pay for something simply because it is expensive. If one is to carry out this line of reasoning, why not just pass legislation which will require the Federal government to bear the costs for the most expensive diseases?

The Federal government's history of assuming the burden of particular diseases suggests the need for reflection. I believe that it would behoove the Congress to examine some past history before deciding to enact this bill into law. A look at both the history of the Black Lung Program and the End Stage Renal Disease Programs in this regard would be instructive.

The Black Lung Program was originally enacted as Title IV of the Federal Coal Mine Health and Safety Act of 1969 (P.L. 91-173) to compensate coal miners disabled as a result of an ailment known as "black lung", which is pneumoconiosis caused by the inhalation of coal dust. This program has been amended a variety of times. A review of the legislative history of this program reveals that its initial sponsors promised it was a "one-shot" deal just as the sponsors S. 2536 are suggesting that this bill may just be a temporary measure. Let me quote one of the original sponsors of the black lung program reacting to concerns that the Congress was establishing an open-ended program:

> This is a one-shot effort. This is not a continuing compensation arrangement to establish Federal based compensation for this or any other industry. We are only taking on those who are now afflicted with pneumoconiosis in its fourth stage—complicated pneumoconiosis.

I would suggest that we all look at the fact that the scope of this one time only program now goes beyond a "chronic dust disease of the lung arising out of employment in a coal mine" to now include just about any "impairment", because one has worked in a coal mine.

A look at the original cost estimates of this program is also useful. When confronted with a cost estimate by the Social Security Administration that the original program would cost $355 million annually, one of the major sponsors of the program, Mr. Dent stated: "Why, if we gave full compensation to every ex-coal miner and a fur coat to every widow, it could not cost more than $40 or $50 million." Do I need to remind my colleagues that at the end of Fiscal Year 1986, the Federal cost of the program is expected to be $1.7 billion and that the Black Lung Trust Fund is expected to have a deficit of $2.8 billion? This was the Federal government's first approach to funding the costs of a specific disease.

Our second venture was the End Stage Renal Disease Program. Originally estimated to cost $250 million a year, it now costs over $2 billion.

At the time this bill was passed, a junior member of the Finance Committee, Mr. Dole, stated: "I think that the one reservation that could be raised . . . is in approaching some of these catastrophic illnesses on a piecemeal rather than on a broad basis." Today, more than a dozen years later, I think this sentiment still applies. We should look at immunosuppressive drug and other very high cost medical procedures and therapies in terms of catastrophic insurance—an opportunity the Congress will have next year after the Secretary's task force on Catastrophic care issues its present report and recommendations to the President. In terms of equity and rational policy making, I think that approach is far more responsible than the politically expedient decision the Committee has made in approving this legislation.

The majority views attempt to distinguish this bill from previous "single disease" programs. Only brief reflection is needed to show that the Committee's distinctions are, in the colloquial phrase, distinction without a difference.

DAN QUAYLE.

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